REOLIVED CENTRAL FAX CENTER

Customer No. 27061

SEP 1 9 2003

Patent

Attorney Docket No. GEMS8081.041

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Brinsfield et al.

Serial No.

09/689,374

Filed

October 12, 2000

For

Group Art No.

3626

Examiner

Porter, R.

CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10

Mobile Clinical Information System

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RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF MAILED SEPTEMBER 7, 2005

Dear Sir:

Responsive to the Notification of Non-Compliant Appeal Brief mailed September 7, 2005, enclosed is a replacement Appeal Brief, addressing the concerns raised by the Examiner.

U.S. Scrial No. 09/689,374

Any questions regarding this matter may be directed to the undersigned.

Respectfully submitted,

V. Mark Wilkinson Registration No. 48,865 Direct Dial 262-376-5016 jmw@zpspatents.com

Dated:

Attorney Docket No.: GEMS8081.041

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Date: 9/19/C

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Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. §§1.191 AND 1.192

Dear Sir:

This Appeal Brief is being filed in furtherance to the Notice of Appeal faxed to the Board of Patent Appeals on April 13, 2005.

U.S. Serial No. 09/689,374

1. REAL PARTY IN INTEREST

The real party in interest is General Electric Company, an Assignee of the above-referenced application by virtue of the Assignment to GE Medical Systems Information Technologies, Inc., a division of General Electric Company, recorded on December 18, 2000, at reel 011405, frame 0941.

2. <u>RELATED APPEALS AND INTERFERENCES</u>

Appellant is unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellant's legal representative in this Appeal. General Electric Company will be directly affected by the Board's decision in the pending appeal.

3. STATUS OF THE CLAIMS

Claims 1-31 are currently pending and under final rejection and, thus, are the subject of this appeal.

4. STATUS OF AMENDMENTS

No Amendments have been made since the final Office Action mailed January 13, 2005.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is related to "clinical information systems and more specifically, to a two-way, wireless clinical patient information monitoring system and a portable patient monitor." <u>Application</u>, pg. 1.

A wireless, bi-directional, portable patient monitoring device for integration with patient monitoring systems interfaces to receive, process, display, and allow for changes in patient care parameters (56) is disclosed. A communication interface (92) is included to receive patient data (64) from a wireless local area network (WLAN) within a medical care facility (39) and transmit care parameters (64) as needed to the WLAN in response thereto. A processor (70) is connected to the communication interface (92) to process the patient data (64) and the care parameters (64). Furthermore, a display (88) is connected

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to the processor (70) to display the processed patient data (64) in human discernable form and an input device (86) is connected to the processor (70) to allow a change in the care parameters (64) by a health care provider (58). <u>See Id.</u> at pg. 3.

Additionally, "a wireless clinical information management system" (42) is disclosed that "decentralizes patient monitoring by networking information and health care devices." <u>Id</u>. The system (42) includes a portable patient monitor (56) having a processor (70) connected to a communication interface (92) to receive and process patient data (48) and to process and transmit care parameters (64). The system also includes a display (88) to display the patient data (48) and an input device to change (134) the patient care parameters (64). The portable patient monitor (56) has a configuration to allow wireless transport on a health care provider (58) for extended periods. The system (42) further includes a plurality of bedside patient monitors (53, 69) to connect to a plurality of patients (62) and transmit patient data (48) as well as a WLAN coupled to the plurality of bedside patient monitors (56) <u>Id</u>.

Furthermore, a computer program (100) residing in memory (74) of a portable patient monitor (56) is configured to cause a processor (70) carry out a plurality of steps. In particular, the processor (70) is caused to remotely interface (92) to a WLAN to acquire any patient alarms (120) and sound an alarm (124) if a patient alarm occurs (122). Additionally, the processor is caused to allow user silencing (126) of the alarm at the portable patient monitor (56) and at a bedside monitor (53, 69) and display patient data (48). <u>Id. at pg. 3-4</u>.

6. GROUNDS OF REJECTION

In the Final Office Action of January 13, 2005, the Examiner rejected claims 1-31. Specifically, claims 1-7, 9, 12, 14, and 18-22 stand rejected under 35 U.S.C. §102(e) as being anticipated by Maschke et al. (USP 6,221,012). Claim 13 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. Claims 11 and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. in view of Gombrich (USP 4,857,716). Claims 8, 26, and 28-29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. in view of Fuchs et al. (USP

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5,788,646). Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. in view of Ballantyne (USP 5,867,821) and further in view of Official Notice. Claims 15-17 and 25 stand rejected rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. in view of Ballantyne. Claim 23 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al., Ballantyne, Official Notice, and further in view of Fuchs et al. Claims 27 and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al., Fuchs et al., and further in view of Gombrich. Claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al., Fuchs et al., and further in view of Ballantyne.

7. ARGUMENT

REJECTION UNDER 35 U.S.C. §102(e)

The Examiner rejected claims 1-7, 9, 12, 14, and 18-22 under 35 U.S.C. §102(e) as being anticipated by Maschke et al. <u>January 13, 2005, Final Office Action, pg. 2</u>.

Independent Claim 1

The Examiner concluded that Maschke et al. teaches "a wireless bi-directional portable patient monitor comprising a communication interface to receive patient data from a wireless local area network (WLAN) within a medical care facility and transmit care parameters as needed to the WLAN in response thereto," as called for in claim 1. <u>Id.</u> To support the conclusion, the Examiner cited column 3, lines 21-44 of Maschke et al. <u>Id.</u> However, Maschke et al. does not teach or suggest any use of a WLAN.

Maschke et al. teaches that a "portable monitor 102 is detachably coupled to and acquires physiological data signals from a plurality of data acquisition modules." Maschke et al., col. 3, Ins. 22-25. Thus, the reference merely discloses that the use of detachably coupling "is intended to include any manner of communicating the acquired data signals to monitor 102, such as a wireless communication link." Maschke et al., col. 3, Ins. 39-44, (emphasis added). While Maschke et al. states that coupling the portable monitor to data acquisition modules may include "a wireless communication link," there is no teaching or suggestion that the "wireless communication link" be made by way of WLAN, as claimed. Rather, Maschke et al. explicitly teaches in column 11,

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lines 56-57, "Pod 150 includes a *single* coupling 150a to portable monitor 102." <u>Maschke et al., col. 11, lns. 56-57</u>, (cmphasis added). Thus, Maschke et al. teaches that a portable monitor may connect, at any given time, to one data acquisition module from a plurality of data acquisition modules. <u>Id</u>. That is, at best, Maschke et al. teaches that a traditional wired point-to-point connection may be replaced with a wireless point-to-point communication link.

The Examiner cited MPEP §2111.01 to support the Examiner's extension of the definition of a WLAN to "wireless communication link." May 13, 2005, Advisory Action, pg. 2. That is, the Examiner asserted that the broadest reasonable interpretation of a WLAN is "wireless communication between 2 or more computer components." See Id. However, this definition far exceeds the bounds of the plain meaning of a WLAN. Rather, as supported by the above cited definition of a "LAN", a WLAN is a system including an infrastructure that facilitates wireless communication between some or all devices associated with the WLAN and not merely a point-to-point wireless link between two individual devices. See Id.

One skilled in the art will readily recognize that a wireless point-to-point connection is not a WLAN. That is, one of ordinary skill in the art will recognize that a local area network (LAN) requires a <u>network</u> and the associated infrastructure of a network, not a mere point-to-point connection between devices. <u>See Definition of LAN</u>, <u>Dictionary.com (citing The American Heritage Dictionary of the English Language</u>, Fourth Edition).

Additionally, the present application discloses clearly states that "the server 44 is connected peripherally to hospital labs 52, a pharmacy 50, a voice router 54, and to a number of portable patient monitoring devices (PPMs) 56 by a wireless local area network (WLAN)" through which, "simultaneously, the server 44 can access real time data from labs 52 and the pharmacy 50, and can transmit such data to the PPMs 56, keeping the health care providers 58 updated at remote locations." Application, pg 7. On the other hand, the "the detachable coupling of the...pods 150-156" via "a wireless communication link," merely allows a specific pod to communicate with a monitor 102, but in no way teaches or suggests any "network." Maschke et al., col. 3, lns. 40-41.

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Therefore, Maschke et al. does not teach or suggest use of a WLAN or "a communication interface to receive patient data from a wireless local area network (WLAN) within a medical care facility and transmit care parameters as needed to the WLAN in response thereto," as claimed.

The Examiner cannot ignore the plain meaning attributed to terms in the art nor the additional explanation within the application to stretch the meaning of "WLAN" to mean any "wireless communications." Rather, by the very terms that compose the acronym "WLAN", a local area network is required. That is, the teaching of a "wireless communication link" cannot be stretched to assert that it teaches a WLAN. In fact, when properly interpreted, such point-to-point communications teaches away from a LAN. <u>See MPEP §2145</u>. For at least these reasons, Maschke et al. cannot be said to teach or even suggest a WLAN.

Furthermore, Maschke et al. does not teach a bi-directional portable patient monitor having a communications interface configured to transmit <u>care parameters</u> to the WLAN as needed in response to patient data received from the "wireless communication link." Specifically, Maschke et al. teaches the use of DMA channels 344a, 344b for communicating with the data acquisition modules. <u>See Maschke et al.</u>, col. 9, lns. 37-44. Maschke et al. states that the DMA channels 344a and 344b "send commands and timing information to the [data acquisition modules], and receive data and status from them." <u>Id</u>. However, Maschke et al. fails to teach the transmission of <u>care parameters</u> in response to patient data, as claimed. That is, while Maschke et al. teaches receiving data and status from the DMA channels, sending "commands and timing information" to the data acquisition modules over the DMA channels is not tantamount to transmitting care parameters to the WLAN. <u>See Id</u>.

Likewise, since no care parameters are taught as being sent to the "wireless communication link," there is no teaching or suggestion in the reference of transmitting the care parameters to the "wireless communication link" as needed in response to patient data received from the "wireless communication link." In fact, there is no teaching or suggestion that any action is taken in response to the patient data received from the "wireless communication link." Rather, Maschket et al. merely teaches that "commands

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and timing information" can be sent over the bi-directional DMA channels but does not state that such transmission is conditioned upon receiving "patient data." <u>See Id</u>.

The Examiner also concluded that that Maschke et al. teaches "an input device connected to the processor to allow a change in the care parameters by a health care provider" in column 6, lines 34-41; column 11, lines 45-62; and column 15, lines 36-43. January 13, 2005, Final Office Action, pg. 3. However, the cited sections merely describe data transfer between the "portable monitor" and a particular "pod." See Maschke et al., col. 6, Ins. 34-41; col. 11, Ins. 45-62; and col. 15, Ins. 36-43. Maschke et al. teaches a system that utilizes local pods to derive data from a given patient and portable monitors that may individually interface with each pod to extract and display the patient data derived by the pod. See Id. Therefore, Maschke et al. teaches that data stored in the pod or the portable monitor may be transferred back and forth between the two devices. See Id. Maschke et al. is clear that data transfer is only for the purpose of monitoring, hence, the term "portable monitor." <u>Id</u>. This does not include the changing or the ability to change "care parameters," as claimed. See Id. Therefore, Maschke et al. teaches a passive monitoring system and does not teach or suggest any "input device connected to the processor to allow a change in the care parameters by a health care provider," as claimed.

For at least these reasons, claim 1 is patentably distinct from the art of record. As such, claims 2-17 are also patentably distinct from the art of record at least pursuant to the chain of dependency. While claims 2-17 are in condition for allowance at least pursuant to the chain of dependency, since claims 2, 5, and 14 include additional subject matter that is distinguishable from the art of record, at least some these additional distinctions will be addressed in detail.

Claims Dependent Upon Independent Claim 1

With respect to claim 2, the Examiner concluded that Maschke at al. teaches that "the processor decodes the patient data to process and display the patient data and encodes the care parameters to transmit the care parameters to the WLAN," as claimed. <u>January 13, 2005, Final Office Action, pg. 3</u>. As stated above, Maschke et al. fails to teach the transmission of care parameters to the WLAN. Likewise, Maschke et al. fails to

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teach encoding of any parameters for transmission to the WLAN. This point further illustrates that Maschke et al. teaches a point-to-point wireless protocol and not a WLAN because such encoding would be unnecessary when two devices communicate directly rather than over a dedicated network infrastructure, as is the case in Maschke et al. See Maschke et al., col. 3, lns. 21-44. For at least these reasons, claim 2 is patentably distinct from the art of record.

Regarding claim 5, the Examiner concluded that Maschke et al. teaches that "the communication interface is compatible with an existing WLAN," as claimed. January 13, 2005, Final Office Action, pg. 3. Again, as previously addressed, Maschke et al. does not teach or suggest use of a WLAN. Thus, Maschke et al. does not teach or suggest that "the communication interface is compatible with an existing WLAN," as claimed. Furthermore, claim 5 underscores the point that a WLAN is more than a mere "wireless communication link," as taught by Maschke et al. Maschke et al., col. 3, lns. 39-44. That is, claim 5 further clarifies that the WLAN must include additional systems/infrastructure outside of the systems that communicate over the WLAN because claim 5 calls for the WLAN to be "existing." A point-to-point "wireless communication link," by definition, cannot exist or be "existing" when the devices are not in communication. For at least these reasons, claim 5 is patentably distinct from the art of record.

With respect to claim 14, the Examiner asserted that Maschke et al. teaches "a portable patient monitor wherein the processor is programmed to receive patient reports and diagnostic analyses prepared at other locations in the medical care facility to provide the health care provider with the patient reports and diagnostic analyses in real time," as called for in claim 14. January 13, 2005, Final Office Action, pg. 4. Specifically, the Examiner cited column 12, lines 45 to column 13, lines 43 to support the proposition that the "processor receives sensor data." Id. First, claim 14 calls for significantly more than the "processor receives sensor data." Second, the cited section discusses positioning of various switches 13, 15, 42, and 44 as well as the inputs that are included in the input terminals of the various pod designs 150, 156, and 158. Nowhere, does the cited section or Maschke et al. as a whole teach or suggest that "the processor is programmed to receive patient reports and diagnostic analyses prepared at other locations in the medical

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care facility to provide the health care provider with the patient reports and diagnostic analyses in real time," as called for in claim 14. For at least these reasons claim 14 is patentably distinct from the art of record.

Independent Claim 18

The Examiner also rejected claim 18 as anticipated by Maschke et al. <u>January 13</u>, <u>2005</u>, <u>Final Office Action</u>, <u>pg. 4</u>. The Examiner again cited column 6, lines 34-41; column 11, lines 45-62; and column 15, lines 36-43 as teaching "a portable patient monitor having a processor...to process and transmit care parameters" and "an input device to change the patient care parameters." <u>Id</u>. However, as previously shown with respect to claim 1, the cited sections merely describe passive data transfer between the "portable monitor" and a particular "pod" and does not include the changing or the ability to change "care parameters," as claimed. <u>See Maschke et al.</u>, <u>col. 6</u>, <u>lns. 34-41</u>; <u>col. 11</u>, <u>lns. 45-62</u>; and <u>col. 15</u>, <u>lns. 36-43</u>. Therefore, Maschke et al. teaches a passive monitoring system and does not teach or suggest "a portable patient monitor having a processor...to process and transmit care parameters" or "an input device to change the patient care parameters," as claimed.

Additionally, claim 18 calls for "a WLAN coupled to the plurality of bedside patient monitors and the portable patient monitor." Again, Maschke et al. teaches that individual couplings may be made between a portable monitor 102 and a particular pod 150-156 that may be by way of an point-to-point wireless link. However, a WLAN, by definition, includes a "network" and not merely individual or point-to-point communications couplings. See Definition of LAN, Dictionary.com (citing The American Heritage Dictionary of the English Language, Fourth Edition). The "detachable coupling of the data acquisition modules" by a wireless connection, as explicitly defined with one another, by Maschke et al., merely allows a specific portable monitor and a specific pod to communicate but does not teach or suggest the use of any "network." Maschke et al., col. 3, lns. 33-44. Therefore, Maschke et al. does not teach or suggest any WLAN, let alone, "a WLAN coupled to the plurality of bedside patient monitors and the portable patient monitor," as claimed.

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Responsive to these arguments, the Examiner stated that "transmitting care parameters to the 'data acquisition modules'...are not recited in the rejected claims." May 13, 2005, Advisory Action, pg. 2. First, Appellant does not assert that the transmissions are "to the 'data acquisition modules'," as the Examiner asserted. Rather, Appellant argued that Maschke et al. does not teach or suggest "a portable patient monitor having a processor...to process and transmit care parameters" and "an input device to change the patient care parameters." Second, these elements are clearly found within claim 18.

Additionally, the Examiner stated that "it is not entirely clear whether the intended functionalities of 'to receive and process patient data and to process and transmit care parameters...' are supposed to be performed by the patient monitor having a processor or the communication interface, or whether these functions are actually performed at all." May 13, 2005, Advisory Action, pg. 2. Appellant believes claim 18 is very clear that the "portable patient monitor" has a "processor." The processor is connected to a "communications interface." As a result of the processor's connections within the portable patient monitor and to the communications interface, the processor is configured to "process". Specifically, the processor is configured to "process patient data and to process and transmit care parameters." As elements expressly called for in claim 18, the Examiner's questioning of "whether these functions are actually performed at all" is perplexing. Id. Each and every element of a claim must be considered and given meaning. See MPEP §2131. If the Examiner cannot show that the prior art teaches each and every element of a claim, a rejection under 35 U.S.C. §102 cannot be sustained.

The Examiner attempted to equate this uncertainty whether the elements expressly called for in claim 18 to be the result of a claimed intended use. May 13, 2005, Advisory Action, pg. 2. However, claim 18, in part, calls for "a processor connected to a communication interface to receive and process patient data and to process and transmit care parameters." This is not an intended use for the processor but an express limitation that the processor must be configured to operate as claimed. This structure of claim is fully addressed in MPEP §2106 as a statutory product claim. See MPEP §2106. It appears that the Examiner's difficulty understanding the claim is a result of a

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misclassification of the claim as a process of making. However, claim 18 is a system that includes, among other elements, a processor configured as claimed. Once claim 18 is properly interpreted to consider each and every element of the claim, as addressed above, it is clear that claim 18 is patentably distinct from the art of record.

For at least these reasons, claim 18 is patentably distinct from the art of record. As such, claims 19-25 are also patentably distinct at least pursuant to the chain of dependency. While claims 19-25 are in condition for allowance at least pursuant to the chain of dependency, since claim 21 includes additional subject matter that is distinguishable from the art of record, at least some these additional distinctions will be addressed in detail.

Claims Dependent Upon Independent Claim 18

Claim 21 states that "the portable patient monitor is a primary monitoring device and wherein a communication interface of the portable patient monitor is compatible with an existing WLAN." As previously addressed with respect to claim 5, claim 21 underscores the point that the claimed WLAN is more than a mere "wireless communication link." <u>See Maschke et al., col. 3, lns. 33-44</u>. That is, claim 21 further clarifies that the WLAN must include additional systems/infrastructure outside of the systems that communicate over the WLAN because claim 21 calls for the WLAN to be "existing." The point-to-point "wireless communication link," by definition, cannot exist when the devices are not in communications. For at least these reasons, claim 21 is patentably distinct from the art of record.

REJECTION UNDER 35 U.S.C. §103(a)

Claims Dependent Upon Independent Claim 1

In rejecting claims 8, 10, 11, 13, and 15-17 the Examiner not only relied on Maschke et al. but also various combinations of Maschke et al. with Gombrich et al., Fuchs et al., Ballantyne et al. and even Official Notice. Claim 8 calls for the processor to be programmed to allow alarm silencing of a bedside monitor. The Examiner rejected claim 8 under 35 U.S.C. §103(a) as being unpatentable over Maschke in view of Fuchs et

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al. (hereinafter Fuchs). The Examiner stated that Maschke does not expressly disclose that the patient monitoring system includes a processor to silence a patient's bedside alarm and that Fuchs discloses that patient monitoring systems often enable remote silencing of bedside patient alarms. While some patient monitoring systems often enable remote silencing of bedside alarms, the references do not teach a bedside monitor having an alarm. Specifically, pod 150 is taught to optionally include memory for storing alarm limits. Maschke, col. 11, lns. 58-60. However, alarm limits stored in memory do not constitute an alarm. Therefore, pod 150 is not a bedside monitor having an alarm. There is no teaching or suggestion in the prior art of a bedside monitor having an alarm. Although Fuchs discusses remote silencing of bedside patient alarms, there is no suggestion or motivation to combine the references to include an alarm on a data acquisition module/bedside monitor to remotely silence.

Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. and Ballantyne (USP 5,867,821) and further in view of Official Notice. Specifically, the Examiner took Official Notice that VOIP was well known in the art and, therefore, it would have been obvious to one of ordinary skill in the art to modify the patient monitor of Maschke et al. and Ballantyne et al. to permit VOIP. Appellant believes that the necessity to rely on such varying and complex combinations of references and Official Notice is direct evidence that the claimed invention is not taught or suggested by the prior art.

Furthermore, the Examiner's application of Official Notice was inappropriate under the MPEP. Specifically, "for the Examiner to take Official Notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known." MPEP §2144.03. However, MPEP §2144.03 is clear that "such rejections [relying on official notice] should be judiciously applied," be "rare," and be used "[i]n limited circumstances." MPEP §2144.03. Furthermore, "any facts so noticed should be of notorious character and serve only to 'fill in the gaps' in an insubstantial manner which might exist in the evidentiary showing made by the Examiner to support a particular ground for rejection." MPEP §2144.03. Appellant does not believe that the Examiner's use of Official Notice

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was merely to "fill in the gaps." That is, the Examiner took Official Notice of multiple elements of the claims, thereby effectively attempting to fill in apparent "holes" in the rejection rather than "gaps."

The Examiner must cite a reference to support the position should the Appellant traverse the assertion. See MPEP §2144.03. Furthermore, "[i]t is never appropriate to rely solely on 'common knowledge' in the art without evidentiary support in the record as the principal evidence upon which a rejection was based." MPEP § 2144.03 citing In re Zurko, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001).

In the case at hand, Appellant disagreed with the Examiner's use of Official Notice and requested substantiation. <u>See October 4, 2004, Response, pgs. 8-10 and March 14, 2005, Response, pgs. 9-10.</u> Specifically, with respect to claim 10 the Examiner took Official Notice that "VOIP is will known in the art" and Appellant argued that such was not the standard for appropriate use of Official Notice. <u>Id.</u> That is, Appellant stated that it was insufficient to merely allege that VOIP is well known because the Examiner must establish that VOIP was well known at the time of invention and within the context and use claimed. Appellant stated that at the time of invention, VOIP was, in fact, not "well known" in the art for use in the manner claimed at the time the invention was made because the application was filed October 12, 2000. <u>Id.</u> Appellant offered that since the first Office Action was issued four (4) years after the application was filed, perhaps the Examiner did not consider the state of the art in October of 2000 and reiterated, "The requirement 'at the time the invention was made' is to avoid impermissible hindsight." <u>MPEP §2141.01</u>. As such, Appellant traversed the use of Official Notice.

The Examiner stated in response to Appellant's argument that the Examiner's conclusion of obviousness was based on hindsight reasoning that, in the present case, "the Examiner has relied upon the reasoning of one of ordinary skill in the art and motivation pulled from one or more of the cited references to support the holding of obviousness." January 13, 2005, Final Office Action, pg. 19. The Examiner supplied Gallant et al. and Kaffine et al. in support of the conclusion that VOIP was known in the art. See May 13, 2005, Advisory Action, pg. 2.

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In particular, to rebut this argument, the Examiner cited Gallant et al. and Kaffine et al. While Gallant et al. does refer to VOIP as "well known" and Kaffine et al. states that "[t]he browser 142 can include any network application such as... VOIP," the Examiner has not provided any support or reasoning to show that VOIP was so notorious and known at the time of the invention to support the contention that VOIP capabilities would have been obvious to combine with the claimed invention. See MPEP §2144.03. That is, neither Gallant et al. nor Kaffine et al. are related to a mobile clinical patient monitoring system. That is, Appellant does not dispute that disclosure of VOIP can be found the Gallant and Kaffine. However, despite the fact that VOIP is found in Gallant and Kaffine, there is no teaching or suggestion in the prior art used to reject claim 10 that calls for the portable patient monitor comprising a speaker, a microphone, and programming the processor to process data to permit voice-over-internet protocol transfer, and at the time of the invention, Appellant contends that the use of VOIP was not well known in the art for use in the manner claimed.

"A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993)." MPEP §2143.01. The Examiner cannot use Official Notice to sidestep the requirements of establishing a prima facie case of obviousness. That is, the Examiner must affirmatively establish through supported explanation that there is a motivation to make the proffered combination, that the proffered combination has a likelihood of success, and that together the combination teaches or suggests each and every element of the claim. See MPEP §2143.01. The Examiner supplied a reference that teaches VOIP; however, there is no teaching, suggestion, motivation, or objective reason in the prior art used in rejecting claim 10 that supports modification of the prior art to meet the claimed invention. That is, there is no motivation to include, use, or combine the prior art to meet the claimed invention having VOIP merely because VOIP was known. That VOIP was

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known is irrelevant absent some objective reason to combine or modify the prior art to meet the claimed invention. <u>See MPEP §2142</u>. The Examiner has not supplied any objective reason to combine VOIP with the prior art to meet the claimed invention absent hindsight. As such, a *prima facie* case of obviousness had not been met. <u>See Id</u>.

For at least these reasons, claim 10 is patentably distinct from the art of record.

Claims Dependent Upon Independent Claim 18

Claim 23 calls for a processor programmed to process data to permit voice-over-internet protocol (IP) transfer. As stated above with respect to claim 10, a prima facie case of obviousness has not been established because the Examiner has not established a teaching, suggestion, motivation, or objective reason in the prior art or known by one of ordinary skill to support modification of the prior art to meet the claimed invention. <u>See MPEP §2142</u>. Gallant et al. and Kaffine et al. have only been asserted to support that VOIP was known to one skilled in the art but have not been asserted in a rejection of claim 23. As previously shown, the Examiner cannot sidestep the burden of establishing a prima facie case of obviousness through Official Notice. <u>MPEP §2142 and 2143.01</u>.

Independent Claim 26

Regarding claim 26, the Examiner cited a variety of sections of Maschke et al. as teaching "remotely interface to a WLAN to acquire any patient alarms" and "sound an alarm if a patient alarm occurs." <u>January 13, 2005</u>, <u>Final Office Action</u>, <u>pg. 9-10</u>. However, as previously shown, Maschke et al. does not teach or suggest any WLAN. Furthermore, Maschke et al. does not teach or suggest the acquisition or sounding of any patient alarms through any interface, remotely via a WLAN, or otherwise.

The Examiner cited column 6, lines 59-64 and column 12, lines 30-38 as "teaching" the claimed acquisition and/or sounding of patient alarms. <u>Id.</u> at pg. 9. However, the cited sections merely states:

Processor PCOB 200 controls the acquisition of data from the pods and cartridges, the processing of patient data, display of parameters and waveforms, alarms and EthernetTM and multi-vendor connectivity.

Maschke et al., col. 6, lns. 59-64 (cmphasis added).

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Lastly, pod 150 receives data representative of pulse and oximetry. Oximetry data representing the saturation, or fraction of oxyhemoglobin to functional hemoglobin (SPO₂ in %O₂) are collected using absorption spectrophotometry.

As shown in FIG. 1b, pod 150 includes two proximately located switches 13 and 15. Switch 13 is coupled to a circuit which transmits a signal to monitor 102 causing monitor 102 to condition itself to start the cardiac output procedure (e.g., perform range and <u>alarm</u> limit adjustments).

Maschke et al., col. 12, lns 30-38 (emphasis added).

It is apparent from a review of these cited sections of Maschke et al. that no computer program to cause a processor to "remotely interface to a WLAN to acquire any patient alarms" and "sound an alarm if a patient alarm occurs" is taught or suggested. Rather, it appears the cited sections were merely the result of a text search for the word "alarm". However, it is clear that these two instances of the word "alarm" do not teach or suggest any computer program to cause a processor to "remotely interface to a WLAN to acquire any patient alarms" and "sound an alarm if a patient alarm occurs," as claimed.

In fact, the Examiner acknowledged that "Maschke...does not expressly disclose that the patient monitoring system includes a processor/program to silence a patient's bedside alarm," as claimed. <u>July 6, 2004, Office Action, pg. 10</u>. Accordingly, the Examiner cited column 1, lines 19-34 of Fuchs et al. as providing a basis to modify the system of Maschke et al. to include such. <u>Id</u>. However, Fuchs et al. teaches the very centralized monitoring systems including the limitations identified in the Background of the Invention Section of the present Specification and overcome by the present invention. <u>See</u> Application, pgs. 1-2. Specifically, the cited section of Fuchs et al. states:

In hospitals and other health care environments of the type having a plurality of patient monitors, it is common to have a central review station coupled to receive the physiological signals acquired from a plurality of patient monitors, in order that physiological signals from a plurality of patients can be reviewed or monitored at a single, central location. Such central review stations have been in use for many years, such as those referred to as a "nurses" station or a "workstation" (referred to hereinafter as a central station). From such stations a clinical user can review patient waveforms, vital signs, trend information and other patient data. Central stations also typically remotely annunciate alarms for assigned bedsides, thereby alerting the clinical staff to a potential emergency, and allow

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remote control of bedside physiological alarm limits and bedside alarm silencing.

Fuchs et al., col. 1, lns. 19-34 (emphasis added).

Similarly, the Background of the Invention Section of the present Application states:

Clinical patient monitoring systems generally consist of individual patient monitoring terminals connected to a centralized monitoring system staffed by a nurse or clinician. The <u>centralized</u> character of these systems allows a small number of caregivers to monitor a large number of patients. The patient monitor terminals typically stationed in the patients' rooms register activity such as heart rate, ECG, respiratory patterns, and other pertinent signs. In addition, drug infusion devices stationed by the patient deliver regulated dosages as prescribed and programmed by doctors and nurses. For bedside monitoring, these devices work adequately. However, patient mobility is hindered and becomes a hazard when transporting the bulky, inelegant bedside patient monitoring systems.

Application, pg. 1 (emphasis added).

Therefore, Fuchs et al. teaches the very centralized monitoring systems including the limitations identified in the Background of the Invention Section of the present Specification that are overcome by the present invention. <u>See Fuchs et al.</u>, col. 1, lns. 19-34 and Application, pg. 2. Accordingly, Fuchs et al. teaches away from the claimed capability to "remotely interface to a WLAN to acquire any patient alarms" and "sound an alarm if a patient alarm occurs" by requiring the very prior art "centralized review stations" that the claimed portable patient monitors seek to improve upon. Therefore, the rejection is improper. <u>See MPEP §2145</u>.

However, in an attempt to rebut these clear shortcomings of the rejection, the Examiner again cited column 1, lines 19-34 and stated that since "Fuchs discloses patient monitoring systems that sound alarms when a patient alarm (e.g. emergency) occurs and further discloses that patient monitoring systems often enable remote silencing of bedside patient alarms...it would have been obvious to one of ordinary skill in the art to modify the method/system of Maschke with the teaching of Fuchs to provide alarms when patients experience emergencies and to allow the user to remotely silence patient bedside alarms." May 13, 2005, Advisory Action, pg. 2. The Examiner's statements make clear

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that the Examiner failed to consider that which is actually claimed. That is, as shown above, Fuchs et al. teaches away from the claimed capability to "remotely interface to a WLAN to acquire any patient alarms" and "sound an alarm if a patient alarm occurs" by requiring the very prior art "centralized review stations" that the claimed portable patient monitors seek to improve upon.

Furthermore, like Maschke et al., Fuchs et al. does not teach any WLAN or other system for communicating patient data and alarms over the WLAN to remote patient monitors, as claimed. Therefore, neither Maschke et al. nor Fuchs et al. teach or suggest "remotely interface[ing] to a WLAN to acquire any patient alarms" and "allow user silencing of the alarm at the portable patient monitor and at a bedside monitor," as claimed. Rather, while, as acknowledged by the Examiner, Maschke et al. does not teach or suggest such an ability to remotely silence an alarm from a portable patient monitor, Fuchs et al. teaches away from such an ability by requiring the very prior art "centralized review stations" that the claimed portable patient monitors seek to improve upon. <u>See July 6, 2005, Office Action, pg. 10 and Fuchs et al., col. 1, lns. 19-34.</u>

For at least these reasons, claim 26 is patentably distinct from the art of record. Accordingly, claims 27-31 are also in condition for allowance pursuant to the chain of dependency.

Claims Dependent Upon Independent Claim 26

With respect to claim 29, the Examiner cited column 3, lines 21-44 and column 8, lines 27-47 as teaching or suggesting that "the computer program further causes the processor to relay patient admission and discharge information to the WLAN." January 13, 2005, Final Office Action, pg. 10. However, as stated above, Maschke et al. does not teach or suggest a WLAN. In fact, Maschke et al. teaches away from a WLAN by teaching a point-to-point "wireless communication link." Maschke et al., col. 3 and lns. 21-44 and See MPEP §2145. Furthermore, the cited sections do not support the rejection. First, column 3, lines 21-44 of Maschke et al. are directed to an overview of pod, cartridge, and sensor communication and do not mention admission or discharge. Additionally, column 8, lines 27-44, while actually mentioning "admission" and

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"checkout", teaches away from "the computer program further causes the processor to relay patient admission and discharge information to the WLAN," as called for in claim 29. That is, the cited section states:

Typically, memory card 106 will be used when transferring patient data between two different portable monitors 102...[but] [a]nother possible use of memory card 106 may be to associate a respective card with each patient from admission to checkout, providing rapid access to the patient's history at any time during his or her stay in the hospital. When used for this purpose, memory card 106 may remain in portable monitor 102 at all times between patient admission and discharge, except when the card is transferred between two portable monitors. All patient trend data would be stored, in a particular memory card and continuously upgraded at appropriate intervals.

Maschke et al., col. 8, lns. 27-44.

Therefore, the cited section does not teach or suggest relaying admission and discharge information to the WLAN, as called for in claim 29. Rather, the section teaches away from such by teaching that a memory card 106, not a WLAN, may be used to transfer patient histories, not admission and discharge information, during the patient stays. *Id*.

For at least these reasons, claim 29 is patentably distinct from the art of record.

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CONCLUSION

In view of the above remarks, Appellant respectfully submits that the proffered rejections are unsupportable. For at least the reasons articulated above, Appellant believes the claims define over the art of record.

Respectfully submitted

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Dated: September 19, 2005

Attorney Docket No.: GEMS8081.041

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APPENDIX OF CLAIMS ON APPEAL

- 1. (Original) A wireless bi-directional portable patient monitor comprising:
- a communication interface to receive patient data from a wireless local area network (WLAN) within a medical care facility and transmit care parameters as needed to the WLAN in response thereto;
- a processor connected to the communication interface to process the patient data and the care parameters;
- a display connected to the processor to display the processed patient data in human discernable form; and
- an input device connected to the processor to allow a change in the care parameters by a health care provider.
- 2. (Original) The portable patient monitor of claim 1 wherein the processor decodes the patient data to process and display the patient data and encodes the care parameters to transmit the care parameters to the WLAN.
- 3. (Original) The portable patient monitor of claim 1 wherein the portable patient monitor is a primary monitoring device.
- 4. (Original) The portable patient monitor of claim 1 wherein the processor processes the patient data to display ECG and vital sign data for a selected patient.
- 5. (Original) The portable patient monitor of claim 1 wherein the communication interface is compatible with an existing WLAN.
- 6. (Original) The portable patient monitor of claim 1 wherein the portable patient monitor is packaged within a housing that is transportable on a health care provider for extended periods.

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- 7. (Original) The portable patient monitor of claim 6 having a length of approximately 7" (17.8 cm), a width of approximately 3.75" (9.5 cm), and a thickness of approximately 1.0" (2.54 cm).
- 8. (Original) The portable patient monitor of claim 1 wherein the processor is programmed to allow alarm silencing of a bedside monitor, and admit and discharge patients.
- 9. (Original) The portable patient monitor of claim 1 wherein the processor is programmed to allow adjustment of alarm parameter violation limits.
- 10. (Original) The portable patient monitor of claim 1 further comprising a speaker and microphone, and wherein the processor is programmed to process data to permit voice-over-internet protocol (IP) transfer.
- 11. (Original) The portable patient monitor of claim 1 further comprising a bar code scanning module and a bar code scanner, and wherein the processor is programmed to receive and compare patient data with data obtainable from a centralized database that includes pharmaccutical and patient bar codes to ensure dosage accuracy, and doctor orders.
- 12. (Original) The portable patient monitor of claim 1 wherein the processor is further programmed to interface with non-proprietary networked systems.
- 13. (Original) The portable patient monitor of claim 12 wherein the processor is further programmed to interface with infusion pumps and ventilators.
- 14. (Original) The portable patient monitor of claim 1 wherein the processor is further programmed to receive patient reports and diagnostic analyses prepared at other

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locations in the medical care facility to provide the health care provider with the patient reports and diagnostic analyses in real time.

- 15. (Original) The portable patient monitor of claim 1 further comprising a PDA module to provide PDA functions to the health care providers.
- 16. (Previously Presented) The portable patient monitor of claim 15 wherein the PDA functions at least include a scheduler, reminders, and to-do lists.
- 17. (Original) The portable patient monitor of claim 1 further comprising a microphone and a digital audio recorder module to input a record of patient medical events by the health care provider.
- 18. (Original) A mobile clinical information management system to decentralize patient monitoring comprising:
- a portable patient monitor having a processor connected to a communication interface to receive and process patient data and to process and transmit care parameters, a display to display the patient data, and an input device to change the patient care parameters, the portable patient monitor having a configuration to allow wireless transport on a health care provider for extended periods;
- a plurality of bedside patient monitors to connect to a plurality of patients and transmit patient data;
- a WLAN coupled to the plurality of bedside patient monitors and the portable patient monitor.
- 19. (Original) The system of claim 18 further comprising a plurality of portable patient monitors, each portable patient monitor assigned to a given number of patients.
 - 20. (Original) The system of claim 18 wherein the processor further:

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decodes the patient data to process and display the patient data and encodes the care parameters to transmit the care parameters to the WLAN; and

processes the patient data to display ECG and vital sign data for a selected patient on the portable patient monitor.

- 21. (Original) The system of claim 18 wherein the portable patient monitor is a primary monitoring device and wherein a communication interface of the portable patient monitor is compatible with an existing WLAN.
- 22. (Original) The system of claim 18 wherein portable patient monitor has a length of approximately 7" (17.8 cm), a width of approximately 3.75" (9.5 cm), and a thickness of approximately 1.0" (2.54 cm).
- 23. (Original) The system of claim 18 further comprising a speaker and microphone, and wherein the processor is programmed to:

allow alarm silencing of a bedside monitor;
admit and discharge patients;
adjust alarm parameter violation limits; and
process data to permit voice-over-internet protocol (IP) transfer.

- 24. (Original) The system of claim 18 further comprising:
- a bar code scanning module and a bar code scanner and wherein the processor is programmed to receive patient data encoded in a patient wristband, and to compare patient data with data obtainable from pharmaceutical bar codes and a centralized database to check dosage accuracy and compliance with doctor orders;

wherein the processor is further programmed to interface with infusion pumps and ventilators, and to receive patient reports and diagnostic analyses prepared at remote locations in the medical care facility to provide the health care provider with the patient reports and diagnostic analyses in real time.

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- 25. (Original) The system of claim 18 wherein the portable patient monitor includes a PDA module having PDA functions that include a scheduler, reminders, and to-do lists, and further comprises a microphone and a digital audio recorder module to record an audio input by the health care provider into the microphone and record patient medical events.
- 26. (Original) A computer program residing in memory of a portable patient monitor to cause a processor to:

remotely interface to a WLAN to acquire any patient alarms; sound an alarm if a patient alarm occurs;

allow user silencing of the alarm at the portable patient monitor and at a bedside monitor; and

display patient data.

27. (Original) The computer program of claim 26 wherein the computer program further causes the processor to:

periodically check a recharged battery charge; and display a warning if the rechargeable battery charge is low.

- 28. (Original) The computer program of claim 26 wherein the computer program further causes the processor to allow user adjustment of alarm parameter violation limits.
- 29. (Original) The computer program of claim 26 wherein the computer program further causes the processor to relay patient admission and discharge information to the WLAN.
- 30. (Original) The computer program of claim 26 wherein the computer program further causes the processor to process audio data from a health care provider to record medical history of a patient.

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31. (Original) The computer program of claim 26 wherein the computer program further causes the processor to scan a bar code from a patient ID and compare data obtained therefrom with data on the patient from a main patient database to ensure proper medical treatment.

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APPENDIX REGARDING EVIDENCE AND RELATED PROCEEDINGS

Evidence

Definition of LAN, Dictionary.com (citing The American Heritage Dictionary of the English Language, Fourth Edition)

Related Proceedings

None

ep.19. 2005 4:09PM ZPS GROUP SC	http://cNo.9051.refeP. 30om/scard
Dictionary.com LAN	iearch ∫ dia ○ Web Premium: <u>Sign up ∤ Login</u>
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Pronunciation Key (a-lan')

- 1. Enthusiastic vigor and liveliness.
- 2. Distinctive style or flair.

[French, from Old French eslan, rush, from eslancer, to hurl: es-, out (from Latin ex-. Scc ex-) + lancer, to throw (from Late Latin lance re, to throw a lance, from Latin lancea, lunce).]

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LAN

n: a local computer network for communication between computers; especially a network connecting computers and word processors and other electronic office equipment to create a communication system between offices [syn: local area network, LAN]

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